AF/1743
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Bowman

Appeal No. ----

Application Serial No.: 09/737,185

Group No.: 1743

Filed: 12/14/2000

Confirmation No.: 9139

Examiner: Gakh, Yelena G.

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPELLANT'S BRIEF

MAY IT PLEASE YOUR HONORS:

This brief is pursuant to the Notice of Appeal filed in this case June 28, 2005.

The application is on behalf of a small entity. Pursuant to 37 CFR 1.17, the required fee of $250.00 for filing the Appeal Brief is enclosed. If any Extension of Time or additional fees for the accompanying response are required, the Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account 501923.

This brief is transmitted in triplicate.

Real Party In Interest

The real party in interest in this appeal is the assignee of all rights to the disclosed invention, GBF, Inc.

Related Appeals And Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

Status Of Claims

Claims 1-21, 38 and 40-44 remain in the case with none of the claims being allowed or allowable. Claims 22-37 and 39 were previously cancelled without prejudice. Claims 1-21, 38, and 40-44 are subject to appeal.

Status Of Amendments

No amendment was submitted after the Office Action mailed March 29, 2005.

Summary Of Claimed Subject Matter

Claims of the application are directed to embodiments of a diagnostic specimen system for identifying and controlling biomedical or toxicology specimens and managing information associated with the specimens. The system provides a diagnostic or toxicology specimen container having an electronic memory tags for remote non-contact recording and reading of data stored therein. Other claims are directed to embodiments of a method of using the diagnostic system to manage information associated with the specimens.

In embodiments, the diagnostic specimen system includes a population of biomedical specimen collection vessels, such as the vessel 1, shown in Figure 1. Attached to each of the vessels 1 is a wireless electronic memory tag 3. The tags 3 remain attached to the vessels 1 as each is transported between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, as depicted by the flowchart of Figure 4.

Also, in various embodiments, the memory tags 3 store data representing an identification code for the vessel 1, the identity of the supplier of the vessel 1, and product information about the vessel 1. The data may relate to the specimen donor and identifies the specimen contained in the vessel 1. The data may also define analytical tests to be performed on the specimen. Each vessel 1 may also include an attached label 4 imprinted with an identifying bar code 7. Figures 1 and 5 show these additional features of the system.

In addition, or in the alternative, in some embodiments of the system, each vessel 1 includes an attached label 4 imprinted with an identifying bar code 7, and the memory tag 3 includes a radio frequency transponder 9. In these embodiments, the data may relate to one or more of the specimen donor, a specimen contained in the vessel 1, an encoded electronic signature of the donor, and can also optionally define tests to be performed on the specimen. The tag 3 may also store an encoded electronic signature of the donor of the specimen.

Other claims describe toxicology specimen systems having collection vessels 1 configured to receive and contain a toxicology specimen, tamper indicating seals, and wireless electronic memory tags 3 attached to the vessels. The wireless tags 3 remain attached to the vessels 1 as they are transported. The tags 3 are for non-contact storage and retrieval of information and contain stored data including an encoded electronic signature of the donor of a toxicology specimen.

Yet additional embodiments of a toxicology specimen system are claimed that include a population of collection vessels 1. Each of the collection vessels 1 is configured to receive and contain a toxicology specimen and has a wireless electronic memory tag 3 attached for non-contact storage and retrieval of information. The memory tag 3 contains stored data including an encoded electronic signature of the donor of a toxicology specimen. The population of collection vessels includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility Members of the population are transportable between the facilities and the tag 3 is attached to the vessel 1 such that it remains attached to the vessel 1 as it is transported between facilities.

In other embodiments, the toxicology specimen system may include a biomedical specimen collection vessel 1 and a tamper-indicating, wireless electronic memory tag 3. The tag 3 is attached such that it remains as the vessel 1 is shipped to and between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility. The tag 3 includes a radio frequency transponder for non-contact storage and retrieval of information. In this embodiment, the system also includes data stored on the electronic memory tag 3. The data may include one or more of an identification code for the container; the identity of the supplier of the vessel and product information about the vessel; identifying information about a specimen contained in the vessel and about the specimen donor; definition of the analytical tests to be performed on the specimen in the vessel; and an encoded electronic signature of the donor of the toxicology specimen in the vessel 1. This system may also include a label 4 imprinted with an identifying bar code 7.

Also, a method for electronically storing information on a diagnostic or toxicology specimen vessel 1 and remotely reading information from the vessel 1 includes providing a population of biomedical specimen vessels 1, as shown in Figure 4. Attached to each of the vessels 1 is a wireless electronic memory tag 3. The population of vessels 1 includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility. The method further includes storing data on one of the memory tags 3 at the vessel distribution facility, shipping or distributing population members with the stored data from the distribution facility to the collection facility, and reading the stored information from the electronic memory tag 3 with a

non-contact electronic reader or scanner at a specimen testing laboratory facility. The memory tags 3 remain attached to the vessels during the shipping or distributing.

In an embodiment, the method that is depicted in the flow chart labeled Figure 4 of the application includes collecting a specimen from a donor in the specimen container at the collection facility, and storing information about the specimen, donor, and/or tests to be performed on the specimen on the memory tags 3. The method may also include collecting and storing the electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.

Issues

A. Whether Appellant and U.S. Patent No. 6,535,129 to Petrick ("Petrick") claim the same patentable invention, so that Appellant's declaration under 37 CFR 1.131 can be disregarded.

B. Whether Claims 1-21 and 40-44 are indefinite under 35 U.S.C. 112, second paragraph.

C. Whether Claims 1-4, 6-7, 9-12, 14-15, 18-19, 21, 38, 41, and 44 are anticipated by U.S. Patent No. 6,535,129 to Petrick ("Petrick") under 35 U.S.C. 102(b).

D. Whether Claims 1-2, 6-7, 9-10, 14-15, 18-19, 21, 40-41 and 44 are anticipated under 35 U.S.C. 102(b) by U.S. Patent No. 5,777,303 to Berney ("Berney").

E. Whether Claims 5, 8, and 13 are unpatentable under 35 U.S.C. 103(a) in view of Petrick.

F. Whether Claims 16, 17, 20, 38, 42, and 43 are unpatentable under 35 U.S.C. 103(a) over Petrick in view of U.S. Patent No. 5,613,012 to Hoffman et al. ("Hoffman").

G. Whether Claims 2 and 10 are unpatentable under 35 U.S.C. 103(a) over Berney in view of disclosure of RD 421048 A ("RD 421048 A").

H. Whether Claims 1, 6-7, 9-10, 14-15, 18-19, and 21 are unpatentable under 35 U.S.C. 103(a) over Berney in view of U.S. Patent No. 5,135,313 to Bowman ("Bowman").

I. Whether Claims 3-4 and 11-12 are unpatentable under 35 U.S.C. 103(a) over Berney in view of Bowman, and further in view of EP 1,004,359 A2 to Stevens et al. ("Stevens").

J. Whether Claims 5 and 13 are unpatentable under 35 U.S.C. 103(a) over Berney in view of Bowman and Stevens, and further in view of U.S. Patent No. 5,314,421 to Leuenberger ("Leuenberger").

K. Whether Claim 8 is unpatentable under 35 U.S.C. 103(a) over Bowman, RD 421048 A, Stevens and Leuenberger.

L. Whether Claims 16, 20,and 38 are unpatentable under 35 U.S.C. 103(a) over Berney in view of Bowman, and further in view of U.S. Patent No. 5,948,103 to Fukuzaki ("Fukuzaki").

M. Whether Claim 17 is unpatentable under 35 U.S.C. 103(a) over Berney in view of Bowman, RD 421048 A, Stevens, Leuenberger, Fukuzaki and U.S. Patent No. 6,018,713 to Coli et al. ("Coli").

Grouping Of Claims

Claims 1-21, 38, and 40-44 are independently patentable.

Argument

A. Appellant Does Not Claim the Same Patentable Invention as Petrick and so can swear behind it.

The Patent Office accorded Appellant a filing date of December 14, 2000 for the application that is the subject of this Appeal. After several official exchanges between an examiner and Appellant, an Office Action mailed January 15, 2004, rejected claims of the application for the first time under 35 U.S.C. 102(e) over Petrick, which issued March 18, 2003 on an application filed November 17, 2000. The Office Action contained no statement indicating that Appellant was claiming the same invention as Petrick, though MPEP § 2308.01[1] provides in relevant part:

> If an applicant is claiming the same invention as a patent ... the application should be rejected under 35 U.S.C. 102(e)/103. A statement should be included in the rejection that the patent cannot be overcome by an affidavit or declaration under 37 CFR 1.131 but only through interference proceedings. Note, how-ever, 35 U.S.C. 135(b) and MPEP § 2307. The applicant should also be advised that an affidavit under 37 CFR 1.608(b) or evidence and an explanation under 37 CFR 1.608(b), as appropriate, must be submitted and it should be stated, if applicable, that the patentee has been accorded the benefit of an earlier U.S. application.

In the absence of any such statements from the Examiner, Appellant submitted Rule 1.131 declarations showing invention of the claimed subject matter antedating the filing date of Petrick to remove the reference as prior art.[2] MPEP § 2308.01 further provides in pertinent part:

> If the applicant ... files an affidavit under 37 CFR 1.131, the rejection should be ... made final. The rejection should specify what the count or counts of the interference ... would be. If the applicant still disagrees ... the rejection may be appealed to the Board of Patent Appeals and Interferences, and the question of

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[1] Manual of Patent Examining Procedure, 8th Edition, Revision 2 throughout.

[2] Appellant first responded June 15, 2004 to the Office Action mailed January 15, 2004. The Patent Office then issued a Notice of Non-Compliant Amendment July 6, 2004, to which Appellant responded July 9, 2004. Appellant later also submitted a Supplemental Response to the June 15, 2004 Office Action on July 23, 2004. The declarations swearing behind Petrick are contained in these three submissions following the June 15, 2004 Office Action.

> whether the application and the reference patent are claiming the same invention may be argued on appeal....

However, in response to Appellant's declarations, the examiner did not specify counts of an interference proceeding, cited MPEP § 715 [II.][3] and concluded, without more, that Appellant's declarations were improper because the application 'claim[ed] [a] substantially identical invention to the one *disclosed* in [Petrick].'[4] (emphasis added) The examiner found no fault in the proof that applicant antedates Petrick, relying solely on the "claiming the same patentable invention" rubric to maintain the rejection. Appellant subsequently submitted an Amendment explaining that the declarations of record were proper to remove Petrick as a prior art reference,[5] to which the Examiner responded:

> [I]n claim 7 Petrick discloses "the business form of claim 1, wherein said wireless identification *device is adhered directly to the specimen or to a container containing the specimen*". The specification discloses "medical samples", "automated facility", etc., unambiguously indicating that the invention is related to a plurality of vessels ... [I]t is conventional US patent practice to define a plurality of objects by using a single article "a" in claims. Thus, the examiner considers the reference claiming "the same patentable invention as the application", and therefore the rule of 37 CFR 1.608 should be applied in this case (see MPEP §§ 2306-2308).[6]

The Examiner's failure to comply with the MPEP and misapplication of the "same patentable invention" standard compels Appellant to file this Appeal. The Examiner errs by saying applicant and Petrick claim the same patentable invention. No counts to an interference proceeding have been specified by the Examiner, as is required by MPEP § 2308.01, so Appellant is left only to speculate that that the single count would be Petrick's Claim 7.

37 CFR 1.601(n) states the general rule for determining whether an application is claiming the same patentable invention as a patent thusly:

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[3] Paragraphs 3 of Office Action mailed November 16, 2004.

[4] Paragraph 20 of Office Action mailed November 16, 2004 (Emphasis added).

[5] Amendment filed February 16, 2005 at page 13.

[6] Paragraph 20 of Office Action mailed March 29, 2005.

> Invention "A" is a *separate patentable invention* with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

The predecessor of the Court of Appeals for the Federal Circuit held in *In re Eickmeyer*, 602 F.2d 674, 202 U.S.P.Q. 655 (CCPA 1979) that the PTO cannot deny an applicant an interference on the grounds that the applicant and a patentee are not interfering in fact and also deny the applicant the opportunity to swear behind the patent on the grounds that the applicant is claiming the same invention as the patentee. Accordingly, since an interference in fact requires a two-way analysis of the "same patentable invention" rule 1.601(n), such must also apply to the interpretation of Rule 1.131.

Under the two-way analysis applied by the Trial Section of the Interferences Division of the Board of Patent Appeals and Interferences in *Winter v. Fujita*[7] to determine the existence of an interference-in-fact, the claimed invention of Petrick is presumed to be prior art in the first step of the analysis. If Appellant's claim is new and non-obvious in view of Petrick's claim, the claims describe separate patentable inventions. If not, Appellant's claim is presumed to be prior art to Petrick's, and the reverse analysis is performed as a second step. If Petrick's claim is new and non-obvious in view of Appellant's claim, the claims describe separate patentable inventions. The claims describe the same patentable inventions only if Petrick's claimed invention anticipates or renders obvious Appellant's claimed invention *and* vice versa.[8] The analysis refers only to the parties' claims, not the remainder of the specifications.

1. Evaluation of Applicant's System claims 1-17 and 40-43.

Petrick's Claims 1 and 7 read:

> 1. A business form comprising:
>
> a first portion providing chain of custody information therein; and
>
> a second portion linking said form with at least one specimen;

[7] 53 USPQ2d 1234, 1243 (1999), reh'g denied, 53 USPQ2d 1478 (BPAI 2000).

[8] Id.

> wherein said business form further includes a wireless identification device associated therewith that electronically provides at least an identifier in response to a query for automatically establishing the chain of custody of said specimen, said wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form.
>
> 7. The business form of Claim 1 wherein said wireless identification device is adhered directly to the specimen or to a container containing the specimen.

And Appellant's Claim 1 states:

> A diagnostic specimen system comprising a population of biomedical specimen collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities.

(a) Assuming Petrick is Prior to Applicant for 1.601(n) test

Assuming Petrick's claim is prior art, Appellant's claim is novel. Appellant's claim describes a population of collection vessels having members at specified locations. Petrick's claim does not disclose multiple vessels at the specified locations. Appellant's claim is therefore new in view of Petrick's claimed invention.

Nor is Appellant's diagnostic specimen system an obvious variation of Petrick's business form. Nothing in Petrick's claim teaches or suggests the vessels at various locations set forth in Appellant's claim. Thus, Appellant's claim is not an obvious variation. Appellant's claim is not even directed to the same subject matter. Petrick claims a business form; Appellant claims a system comprising a population of vessels. Therefore, Appellant is not claiming the same patentable invention as Petrick's Claim 7.

(b) Assuming Applicant is prior to Petrick for 1.601(n) test

If Appellant's claim is assumed to be prior art to Petrick's, the same result obtains. Petrick's claim requires a new business form having two portions and a particular association

between the business form and the wireless identification device. Appellant's claim does not disclose or suggest a business form (much less one having two portions) or any particular relationship between such a form and an identification device.[9] Thus, Petrick's claim is non-obvious in view of Appellant's claim and the inventions are separately patentable under the *Winter* analysis.

Even if the Board eschews *Winter* and risks violating the rule of *Eickmeyer* by applying the test as one-way only, applicant is not claiming the same invention as Petrick. Appellant's claim is new and non-obvious when Petrick's claim is presumed to be prior art.

The PTO often asserts that inventions are patentably distinct and supportive of two patents in making restriction requirements. According to MPEP Section 808.02 separate classifications is a reason for insisting on restriction of distinct inventions. Petrick is classified in U.S. Class 340/572.1, relating to electrical communications. Completely unrelated to electrical communications is U.S. Class 436/56, where applicant's published application has been classified.

2. Evaluation of Appellant's method claims 18-21, 44

Furthermore, Appellant's Claim 18 reads:

> A method for electronically storing information on a diagnostic or toxicology specimen vessel and remotely reading information from the vessel comprising:
>
> providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached thereto, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility;
>
> electronically storing data on one of the electronic memory tags at the vessel distribution facility;
>
> shipping members including the electronic memory tags attached thereto with electronically stored data from the vessel distribution facility to the specimen collection facility; and
>
> reading the stored information from the electronic memory tag with a non-contact electronic reader or scanner at a specimen testing laboratory facility.

[9] This is so although Appellant's claim is broad enough to be infringed by a device having the features described by Petrick's claim. While some embodiments of Petrick could be implemented to infringe Claim 1, and *vice versa*, such infringements are not inevitable. If a practitioner of Appellant's Claim 1 does not use a business form, Petrick is not infringed. If a practitioner of Petrick does not have containers at the locations of Appellant's Claim 1, Appellant's Claim 1 is not infringed.

The Examiner apparently asserts that Appellant's Claim 18 and Petrick's Claim 7 claim the same patentable invention, although Appellant's claim describes a method of storing information, and says nothing about the business form that is Petrick's invention. Furthermore, Appellant's method includes storing data on its tags at a vessel distribution facility, while Petrick's claim says nothing about such a facility. Applicant's method claims have no disclosure or suggestion of a two-part business form as claimed by Petrick. Therefore, Appellant's Claim 18 is not claiming the same patentable invention as Petrick's Claim 7.

The Examiner insists that Appellant and Petrick claim the same patentable invention without specifying what the count or counts of an interference would be, as is required under 37 CFR 1.131. No doubt the Examiner has not done so because the task is impossible: Appellant is not claiming the same patentable invention as Petrick. Therefore, Appellant can properly swear behind Petrick, and the rejections of Appellant's application using Petrick as prior art should be reversed.

B. The Scope of Claims 1-21 and 40-44 is Definite under 35 U.S.C. 112, Second Paragraph.

The Examiner rejected Claims 1-21 and 40-44 as indefinite, asserting that the claims are not directed to statutory subject matter.[10] The Examiner also apparently objected to certain of Appellant's claim limitations as not limiting the scope of its claims.[11] Finally, the Examiner concluded that since certain of Appellant's claim limitations allegedly do not limit the structure of Appellant's claimed specimen vessels, the limitations would not be considered.[12]

The MPEP requires that definiteness of claim language be analyzed in light of the content of the particular application disclosure, the teachings of the prior art, and the claim

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[10] Paragraph 4 of Office Action mailed March 29, 2005. ('According to 35 U.S.C. 101, patentable inventions are related to "any new and useful process, machine, manufacture, or composition". It is not clear, which category of this four the claimed subject matter belongs to.').

[11] Id. ('*Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a* ***particular structure*** *does not limit the scope of a claim or claim limitation.*').

[12] Id. ('The examiner concludes that since the location of the vessels does not further limit their structure, the limitation recited in the independent claims after "wherein" does not bear any patentable weight.')

interpretation that would be given by one of ordinary skill in the art at the time of the invention.[13] Figure 5 of Appellant's application illustrates a specimen container supplier, a specimen collection site, and a laboratory. One of ordinary skill in the art would appreciate that these elements correspond to Appellant's claimed facilities from reading Appellant's disclosure.[14] It is clear, to answer the examiner, that the claims cover a manufacture, one of the statutory classes. Thus, Appellant states the subject matter it regards as the invention with a *reasonable* degree of clarity and particularity so that one of ordinary skill in the art would understand the scope of the claims.[15]

The Examiner also raised various hypothetical questions,[16] all of which can be addressed by simply reading Appellant's claim language. For example, the Examiner has asserted that, from Appellant's claim language, one would not understand whether a vessel in transport falls within scope of the claim language.[17] Appellant's claims do not claim vessels in transport. One of ordinary skill would understand that the claimed population includes vessels at specified locations that are *transportable* between the locations. Despite the Examiner's protestations, the use of clear functional language to define the scope of protection sought is perfectly acceptable,[18] so long as the language describes subject matter with a *reasonable* degree of clarity and particularity.[19] Potential infringers need to be able to tell if they infringe or not, and they certainly would have no difficulty on that score.

The examiner chooses to disregard the claim recitations that members of the population being claimed are located as defined locations. Such claiming may be unconventional but it is not non-statutory and the examiner is not free to disregard it. Claims

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[13] MPEP 2173.02.

[14] See, for example, page 8, line 14 – page 9, line 3; page 12, line 25; page 13, line 23; page 14, line 17.

[15] See MPEP §2171 (Emphasis added).

[16] Paragraph 3 of Office Action mailed November 16, 2004; Paragraph 4 of Office Action mailed March 29, 2005.

[17] 'If the vessels are moving and changing their location, how can such a system be definite?' Paragraph 3 of Office Action mailed November 16, 2004; Paragraph 4 of Office Action mailed March 29, 2005.

[18] MPEP§ 2173.01.

[19] See MPEP § 2173.02.

frequently recite elements n various positions, and those positions are attributes of the elements that are given weight in the evaluation of patentability.

Appellant's claim language is reasonably clear and particular, so that one of ordinary skill would understand the scope of the claimed subject matter. Therefore, Appellant's claims are not indefinite, and each of the rejections of Claims 1-21 and 40-44 under 35 U.S.C. 112, second paragraph, is improper. The rejection of each claim should be reversed.

C. Petrick does not Anticipate Claims 1-4, 6-7, 9-12, 14-15, 18-19, 21, 38, 41, and 44.

Appellant's claims describe a specimen system that includes a population of collection vessels, each configured to receive and contain a specimen. The population includes members located at a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory. The members are transportable between the facilities and the vessels have wireless electronic memory tags attached so that the tags remain as the vessels are transported between facilities.

Petrick discloses a chain of custody form provided with a radio frequency identification chip and further discloses a data collection process achievable with the form. Petrick's process includes recording information on the chip as a sample is transferred to a collection custodian, an intermediate custodian, and a laboratory. Petrick says nothing about a vessel distribution facility, or members of a population of vessels located there.

Petrick anticipates Appellant's claims only if each and every element as set forth in the claim is found either expressly or inherently described in Petrick.[20] The reference does not disclose a population of vessels including members at each of Appellant's specified locations. Therefore, Petrick does not anticipate Claim 9. Moreover, since Petrick is NOT prior art, having been sworn behind, these rejections are improper, and should be reversed.

D. Berney does not Anticipate Claims 1-2, 6-7, 9-10, 14-15, 18-19, 21, 40-41 and 44.

Berney discloses a system for registering useful information during analyses of blood in conventional glass test tubes 1.[21] Berney's electronic memory labels 4 are attached to

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[20] MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

[21] Column 1, Line 11 of Berney.

supports 31 that are fixed on the test tubes 1 in a testing laboratory at the time of sample analysis.[22] The supports 31 rest on a base 33 including a bus system 46 for transferring information to and from the labels 4 during analysis.[23] Berney does not disclose and is not concerned with vessels at a vessel distribution facility, a specimen collection facility and a specimen testing laboratory facility. Instead, Berney's system provides a temporary mount to a test tube during analysis of the test tube contents in a laboratory – only the last of the three locations of applicant's claims.

Berney anticipates Appellant's claims only if each and every element as set forth in the claims is found either expressly or inherently described.[24] The Examiner concludes that Berney inherently discloses Appellant's claimed population of biomedical specimen collection vessels.[25] But, to be inherent, the features of Appellant's claimed invention *must necessarily be* present in the Berney disclosure.[26] Appellant's population of vessels having members at the specified locations is not even consistent with Berney's disclosure, much less, *necessarily present*. One of ordinary skill would read that Berney's label's attachment to the test tubes is temporary with the labels attached to the test tubes in the lab and removed in the lab. Accordingly, Berney neither explicitly nor inherently discloses any of Appellant's Claims 1-2, 6-7, 9-10, 14-15, 18-19, 21, 40-41 and 44. The Examiner's rejections of these claims as anticipated by Berney should be reversed.

E. The Examiner Failed to Establish That Claims 5, 8, and 13 are *Prima Facie* Obvious in View of Petrick.

A rejection of a claim in a utility application under 35 U.S.C. § 103(a) based on combinations of prior art references is a legal conclusion which must be based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary

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[22] Col 1, Lines 35-38 of Berney; Column 1, Lines 64-65 of Berney; Column 2, Lines 28-29. (Emphasis Added).

[23] Col 2, Lines 34-56 and Figures 3 and 4 of Berney.

[24] MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

[25] Paragraph 7 of Office Action dated 3/29/2005.

[26] MPEP § 2112 (IV.).

skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of obviousness. The references must provide one of ordinary skill a motivation to combine their respective elements to yield the claimed invention. *In Re Dembiczak*, 50 U.S.P.Q. 2d 1614 (Fed. Cir. 1999).

In the case of *In re Lee*, 61 U.S.P.Q. 2d. 1430, 277 F3d 1338 (Fed. Cir. 2002), the court indicated that the findings under 35 U.S.C. 103 must be based on reasoned findings that one of ordinary skill in the art would have been motivated to select and combine the references. The Court further indicated that the findings and the grounds thereof must be clearly indicated on the record. And the evidence must come from the references, not the examiner's hindsight-based guesswork:

> With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion. 61 USPQ2d at 1434

The Examiner also concludes that it would have been obvious to store data including the identity of a specimen vessel and product information about the vessel on a memory tag. One of ordinary skill would allegedly modify Petrick to include such information 'because vessels (containers) from different suppliers may vary, and therefore such information is important for handling them properly, and because information on a supplier is always conventionally provided with products.'[27] The Examiner cited no authority for this position. Subjective belief and unknown authority are not proper substitutes for evidence bearing on the

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[27] Paragraph 11 of Office Action mailed March 29, 2005.

question whether one of ordinary skill would have combined the references to produce Appellant's claimed inventions.[28] In this case, the record is devoid of objective evidence supporting the Examiner's mere conclusory statements. Therefore, the Examiner has failed to establish a *prima facie* case that Claims 5, 8, and 13 would have been obvious in view of Petrick, so the obviousness rejections should be reversed. Of course, the rejections should also be reversed because Petrick is not prior art.

F. Claims 16, 17, 20, 38, 42, and 43 are not Obvious over Petrick in View of Hoffman.

Hoffman discloses an identification system for determining an individual's biometrics sample and personal identification code gathered during a bid step with biometrics sample and personal identification code for that individual gathered during a registration step and stored at a remote site wherein there is a data processing center. Biometric input data is preferably encrypted and sealed.

The Examiner asserts that one would combine the electronic signature disclosed in Hoffman with Petrick's disclosure because doing so would be 'an obvious improvement over hand-written document and because electronic submission of the forms suggested by Petrick assumes electronically encoded signature.'[29] But subjective belief and unknown authority are not proper substitutes for evidence of obviousness and thus do not support a *prima facie* case of obviousness.[30] The Examiner has not pointed to objective evidence of obviousness, and has thus failed to show that Claims 16, 17, 20, 38, 42, and 43 would have been an obvious combination of Petrick and Hoffman. Moreover, the proposed combination of eliminating handwritten forms would destroy the very essence of Petrick – a business form that one writes on! Each of these rejections should therefore be reversed, in addition to reversal on the grounds that Petrick is not prior art.

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[28] In re Lee, 277 F.3d at 1342-44, 61 USPQ2d at 1433-34.

[29] Paragraph 12 of Office Action mailed March 29, 2005.

[30] In re Lee, 277 F3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002).

G. Claims 2 and 10 are Patentable over Berney in view of RD 421048A.

To establish a *prima facie* case of obviousness, a combination of prior art references must teach or suggest all the limitations of the allegedly obvious claimed invention.[31] Berney does not teach or suggest a specimen system including a population of vessels having members located at a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory. RD 421048A discloses a method for chemical management for tracking compounds within a chemical synthesis system including identification tags having passive transponders.[32] Modifying Berney to include RD 421048A's passive transponders does not produce the diagnostic specimen system of Appellant's Claims 2 and 10. RD421048A still does not disclose applicant's claimed vessel locations. Thus, the Examiner has also failed to establish a *prima facie* case of obviousness of Claims 2 and 10. So, the rejection of each of Claims 2 and 10 as obvious over Berney in view of RD 421048A should also be reversed.

H. Claims 1, 6-7, 9-10, 14-15, 18-19, and 21 are Patentable over Berney in View of Bowman.

To establish a *prima facie* case of obviousness, a combination of prior art references must teach or suggest all the limitations of the allegedly obvious claimed invention.[33] The examiner cites Bowman's chain of custody bag 10 including a removable specimen label 28. Neither Berney nor Bowman teaches or suggests a specimen system including a population of vessels having members located at a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory. Furthermore, the methods described by Claims 18, 19, and 21 of Appellant's application are not *necessarily* present in either reference, and are thus not inherently disclosed.[34] Therefore, each of Claims 1, 6-7, 9-10, 14-15, 18-19, and 21 is in condition for allowance. The rejection of each of these claims should be reversed.

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[31] MPEP 2143 citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

[32] RD 421048 A at ABSTRACT.

[33] MPEP 2143 citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

[34] MPEP § 2112 (IV.).

I. Claims 3-4 and 11-12 are Patentable over Berney in View of Bowman, and Further in View of Stevens.

Stevens discloses a sample collection tube 20 and a label 40 comprising a permanent portion 50 having a barcode 90 and a peel away portion 70 for affixation to a test request form or to another container or item.[35] The Examiner asserts that it would have been obvious to combine the barcode of Stevens with a version of Berney having a modified electronic tag by adding a label "to 'create a link between the container, the patient, and the test request forms', or any other forms associated with using this container."[36] Berney discloses an electronic label that that provides for registration of *all* useful information required for analysis of a blood sample, however, and thus *eliminates* the need for jotting down and manual transfer of information.[37] Combining Stevens' barcode associated with a manual entry form or another container with the Examiner's modified version of Berney would destroy Berney's purpose of eliminating manual entry of information. Also, the result would still not have vessels at applicant's recited locations. Thus, one of ordinary skill would not modify the references as proposed by the Examiner.[38] Accordingly, the obviousness rejection of each of Claims 3-4 and 11-12 is improper and should be reversed.

J. Claims 5 And 13 Are Patentable Over Berney in View of Bowman and Stevens, and Further in View of Leuenberger.

Leuenberger discloses a microporous plastic film label 12 for a blood pack 10. The reference also discloses supplying a manufacturer's product code and lot number with blood packs.[39] The Examiner asserts that it would have been obvious to include such information on Petrick's electronic memory labels to 'because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and

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[35] Stevens at column 5, lines 25-27; column 6, lines 19-21; Figure 8.

[36] Paragraph 15 of Office Action mailed March 29, 2005 quoting Bowman at Column 1, Line 13-18.

[37] Berney at column 1, lines 30-32.

[38] MPEP 2143.

[39] Leuenberger at column 1, lines 17-18.

because information on a supplier is always conventionally provided with products,'[40] despite the absence of a suggestion arising from the references to store product information on Berney's electronic memory tags. Berney's label is affixed to a test tube and data entered during the time of analysis in a testing laboratory.[41] One of ordinary skill would have no reason to enter test tube product information on Berney's labels at the testing laboratory. Therefore, one of ordinary skill would not store the product information disclosed in Lueunberger on the electronic memory tags disclosed in Berney, and Appellant's Claims 5 and 13 are both in condition for allowance.

K. Claim 8 is Patentable over Berney, Bowman, RD421048A, Stevens and Leuenberger.

The Examiner further asserts that it would have been obvious to include product information on a thrice-modified version of Berney 'because, first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container.'[42] Neither of these proffered motives, however, explains why one would be motivated to store supplier information *on an electronic memory tag*, as Appellant claims. Thus, they are merely unsupported allegations that fail to address the question whether one of ordinary skill would have been motivated to combine the references to produce the *claimed invention*. Arguments made above are also applicable here. Therefore, the Examiner has failed to present a *prima facie* case of obviousness with respect to Claim 8, and the rejection of this claim should be reversed.

L. The Examiner Failed to Establish That Claims 16, 20,and 38 are Prima Facie Obvious over Berney in View of Bowman, and Further in View of Fukuzaki.

The claims recite the inclusion of an electronic signature of a donor of a toxicology specimen.

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[40] Paragraph 16 of Office Action mailed March 29, 2005.

[41] Berney at Column 1, Lines 34-38.

[42] Paragraph 17 of Office Action mailed March 29, 2005.

Fukuzaki discloses an electronic document security system including means for modifying a seal or signature with characteristic data of the document.[43] The Fukuzaki electronic signature is for use on documents transmitted by electronic means. The Examiner concludes that information contained on an electronic label attached to a toxicology specimen should be secured, and that Fukuzaki provides 'the most convenient way of securing the information.'[44] Thus, where Fukuzaki says to send signatures electronically, the examiner adds a dollop of hindsight without reference to a motivation derived from the references to say it also would be convenient and obvious for tags affixed to toxicology specimen containers. This proffered motivation to combine Berney modified by Bowman with Fukuzaki is nothing more than a subjective belief based on unidentified authority that fails to provide an evidentiary support for the rejections of Claims 16, 20 and 38. Accordingly, the Examiner has failed to present a proper *prima facie* case of obvious with regards to Claims 16, 20 and 38, so each of the rejections should be reversed.

M. Claim 17 is Patentable over Berney in view of Bowman, RD 421048 A, Stevens, Leuenberger, Fukuzaki and Coli.[45]

Subjective belief and unknown authority are not proper substitutes for objective evidence of obviousness.[46] In rejecting Claims 17 of the application as describing an invention that would have been obvious to one of ordinary skill in the art, the Examiner merely recycles the same unsupported conclusory statements previously shown to be improper.[47] Accordingly, the Examiner has failed to present a proper *prima facie* case of obvious with regards to Claims 17, and this rejection should be reversed.

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[43] Fukuzaki at column 2, lines 29-34.

[44] Paragraph 18 of Office Action mailed March 29, 2005.

[45] Although Coli is listed as a reference upon which the rejection of Claim 17 was based in Paragraph 19 of the Office Action mailed March 29, 2005, the examiner does not explain why Coli is cited against Claim 17.

[46] In re Lee, 277 F.3d at 1342-44, 61 USPQ2d at 1433-34.

[47] Paragraph 19 of Office Action mailed March 29, 2005.

Conclusion

The rejections should be reversed.

Respectfully submitted,

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Date: August 29, 2005

File No.: 2552-011

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Appendix

The appealed claims are as follows:

1. A diagnostic specimen system comprising a population of biomedical specimen collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities.

2. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag includes a radio frequency transponder.

3. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including an identification code for the vessel.

4. A diagnostic specimen system as claimed in claim 3 further including a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel.

5. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including the identity of a supplier of the vessel and product information about the vessel.

6. A diagnostic specimen system as claimed in claim 1 wherein an electronic memory tag contains stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

7. A diagnostic specimen system as claimed in claim 6 wherein an electronic memory tag contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

8. A diagnostic specimen system comprising:

a population of collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities;

data stored on an electronic memory tag including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, and definition of the analytical tests to be performed on the specimen in the vessel; and

a label imprinted with an identifying bar code attached to each vessel.

9. A toxicology specimen system comprising a population of collection vessels, each configured to receive and contain a toxicology specimen and having a wireless electronic memory tag attached to the vessel for non-contact storage and retrieval of information,

wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities.

10. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag includes a radio frequency transponder.

11. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including an identification code for the vessel.

12. A toxicology specimen system as claimed in claim 11 further including a label imprinted with an identifying bar code attached to each vessel.

13. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including the identity of the supplier of the vessel and product information about the vessel.

14. A toxicology specimen system as claimed in claim 9 wherein an electronic memory tag contains stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

15. A toxicology specimen system as claimed in claim 14 wherein an electronic memory tag contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

16. A toxicology specimen system as claimed in claim 9 wherein an electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen.

17. A toxicology specimen system comprising:

a population of biomedical specimen collection vessels, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, each vessel having a wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is transported between facilities, the electronic memory tag including a radio frequency transponder for non-contact storage and retrieval of information; data stored on the electronic memory tags including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, definition of the analytical tests to be performed on the specimen in the vessel, and an encoded electronic signature of the donor of the toxicology specimen in the vessel; and a label imprinted with an identifying bar code attached to each vessel.

18. A method for electronically storing information on a diagnostic or toxicology specimen vessel and remotely reading information from the vessel comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached thereto, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility;

electronically storing data on one of the electronic memory tags at the vessel distribution facility;

shipping members including the electronic memory tags attached thereto with electronically stored data from the vessel distribution facility to the specimen collection facility; and

reading the stored information from the electronic memory tag with a non-contact electronic reader or scanner at a specimen testing laboratory facility.

19. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached to the vessel at a vessel distribution facility;

distributing population members including the wireless electronic memory tag attached thereto to a specimen collection facility;

collecting a specimen from a donor in the specimen container at the specimen collection facility; and

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag.

20. A method as claimed in claim 19 further including collecting and storing an electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.

21. A method as claimed in claim 19 further including transporting the member vessel with collected specimen from the specimen collection facility to a specimen testing laboratory and storing the results of the analytical tests performed on the specimen in the vessel on the electronic memory tag at the specimen testing laboratory.

22. – 37 (Canceled).

38. A toxicology specimen system comprising a collection vessel configured to receive and contain a toxicology specimen, a tamper-indicating seal, and wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is transported, the tag for non-contact storage and retrieval of information and wherein the electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen.

39. (Canceled).

40. A diagnostic specimen system as claimed in claim 1 further including an electronic database accessible from the specimen collection facility for storing data entered at the collection facility.

41. A diagnostic specimen system as claimed in claim 40 further including an electronic network connecting the specimen collection facility to the specimen testing laboratory for transmitting data from the collection facility to the testing laboratory.

42. A toxicology specimen system comprising a population of collection vessels, each configured to receive and contain a toxicology specimen and having a wireless electronic memory tag attached to the vessel for non-contact storage and retrieval of information, the memory tag containing stored data including an encoded electronic signature of the donor of a toxicology specimen, wherein the population includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility and wherein the members are transportable between the facilities and the tag is attached to the vessel such that it remains attached to the vessel as the vessel is transported between facilities.

43. A toxicology specimen system comprising:

a biomedical specimen collection vessel and a tamper-indicating, wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is shipped to between a between a vessel distribution facility, a specimen collection facility,

and a specimen testing laboratory facility, the tag including a radio frequency transponder for non-contact storage and retrieval of information;

data stored on the electronic memory tag including an identification code for the container, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, definition of the analytical tests to be performed on the specimen in the vessel, and an encoded electronic signature of the donor of the toxicology specimen in the vessel; and

a label imprinted with an identifying bar code.

44. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached to the vessel, wherein the population includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility, and wherein each of the vessels includes a wireless electronic memory tag attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities;

collecting a specimen from a donor in the specimen vessel at the specimen collection facility;

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag; and

collecting and storing the electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.